OCT 23 2006

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 31-F-0002 **CUSTOMER NO.** 442

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Operational Toxicology Branch
2760 Q St, (b)(2)High, (b)(7)f
Wright-Patterson AFB, OH 45433
(999) 999-9999

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

(b)(2)High, (b)(7)f

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits			16	25	41
9. Non-Human Primates					
10. Sheep					
11. Pigs			24		24
12. Other Farm Animals					
13. Other Animals					
14. Ferrets			13		13

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)

(b)(6), (b)(7)c

AL *(Type or Print)*

DATE SIGNED 13 Oct 06

PART 1 - HEADQUARTERS

(AUG 91)

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation, A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 31 – F - 0002
2. **Number:** 25 rabbits
3. **Species (common name):** New Zealand White Rabbits

4. **Explain the procedure producing pain and/or distress.**

A proprietary protein solution was placed by itself into the eyes of rabbits to determine if it would cause any irritation to rabbit eyes either in a single or repeated application. The right eye of rabbits received 0.1mL of protein solution while phosphate buffered saline (pH 7-7.4) was placed in the left eye. The pH of the protein solution was measured and adjusted to match the pH of the phosphate buffered saline. The procedure was based on the standard Acute Eye Irritation study using the U.S. Environmental Protection Agency (USEPA) Office of Prevention, Pesticides and Toxic Substances (OPPTS) Health Effects Test Guidelines, 870-2400. Solutions of capsaicin ranging from 0.16 to 1.0% were also administered to rabbit eyes. The capsaicin was used to produce a mild to moderate level of irritation. The protein was tested as an antidote to prevent or alleviate the irritation produced by the capsaicin.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and or distress relief would interfere with test results. (For Federally mandated testing, see item 6 below)**

In vitro techniques, considered for this study and discussed in the animal use protocol are still inadequate to test for eye irritation and to examine the efficacy of an antidote to alleviate irritant responses. Exposure to the protein alone was part of actual acute toxicity testing for potential irritation. In order to determine if the protein had the potential to produce irritation, non-anesthetized rabbits needed to be used to ensure that there was no masking, blocking or lessening of potential irritation responses. Rabbits were initially anesthetized prior to exposure to a capsaicin solution. The anesthetic interfered with the irritation response making it impossible to use the capsaicin as an irritant in order to determine if the protein worked as a suitable antidote.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):**

40 CFR 158.340 __X__

Data on primary eye irritation are required by 40 CFR 158.340 to support the registration of each manufacturing-use product and end-use product with the USEPA.